



APR 11 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William J. Griffin  
Regulatory and Clinical Affairs Manager  
Ortho Development Corporation  
12187 South Business Park Drive  
Draper, Utah 84020

Re: K042565

Trade/Device Name: Encompass™ Plasma Sprayed, Press-fit Hip System: Encompass™  
Hip Stem, Tri-plus™ Acetabular Shell, Tri-plus™ DCM Liner

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: II

Product Code: LPH, MBL

Dated: March 11, 2005

Received: March 14, 2005

Dear Mr. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

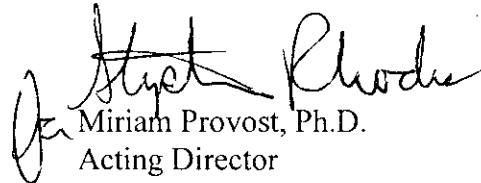
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over the typed name.

Miriam Provost, Ph.D.

Acting Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042565

Device Name: Encompass™ Plasma Sprayed Press-Fit Hip System

Indications for Use

The device is intended for use in total hip arthroplasty. The device is intended for uncemented, press-fit use only.


1. Notably impaired hip joint due to osteoarthritis, rheumatoid arthritis and/or post traumatic arthritis.
2. Previously failed surgery.
3. Proximal femoral neck fractures or dislocation.
4. Idiopathic avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Treatment of fractures that are unmanageable using other forms of therapy.
7. Benign or malignant bone tumors congenital dysplasia or other structural abnormalities where sufficient bone stock exists to properly seat the prosthesis.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-Off)

Division of General Restorative,  
and Neurological Devices

510(k) Number K042565